

We claim:

1. A method for detecting the presence of at least one predesignated, target antibody to a mycobacterium in a sample selected from one or more patient bodily fluids which comprises the following steps: (a) contacting the sample of one or more patient bodily fluids with at least one mycobacterium antigen on a lateral-flow assay membrane to bind to the target antibody in the sample; (b) previously, simultaneously or subsequently to step (a), binding the at least one mycobacterium antigen with a conjugated label producing a detectable signal; and (c) detecting the signal whereby the presence of the target antibody is determined in the sample by the presence of the signal.

2. The method of claim 1, wherein the one or more bodily fluids is selected from the group consisting of saliva, oral rinse expectorant, oral fluid, gingival crevicular fluid, urine, sweat, tears, blood, serum, stool, gastric fluid, synovial fluid, phlegm, culture media and other clinical and laboratory specimens and samples.

3. The method of claim 1, wherein the one or more bodily fluids is saliva or diluted serum.

4. The method of claim 1, further comprising the step of evaluating immunization status of the patient from whom the sample came by comparing the signal or lack thereof with immunizations previously received by the patient and in comparison to a known standard control.

5. The method of claim 1, wherein the mycobacterium antigen specifically binds to mycobacterium tuberculosis specific antibodies.

6. The method of claim 1, wherein the at least one mycobacterium antigen comprises a mixture two or more mycobacterium antigens.

5 7. The method of claim 1, wherein the at least one mycobacterium antigen is selected from the group consisting of 38kDa and 16kDa antigens.

8. The method of claim 1, wherein the membrane has at least a first stripe of the at least one mycobacterium antigen, and a control stripe formed by striping a material that will react with sample antibodies as they flow across the control stripe.

9. The method of claim 1, wherein the membrane has a least a first stripe of at least one mycobacterium tuberculosis antigen, a second stripe of at least one mycobacterium antigen that is different from the mycobacterium tuberculosis antigen of the first stripe, and a control stripe formed by striping a material that will react with sample antibodies as they flow across the control stripe, the second stripe located between the first stripe and the control stripe.

10. The method of claim 9, wherein the second stripe comprises a shared mycobacterial antigen common to all mycobacteria or a mixture of such antigens.

11. An immunoassay kit for detecting at least one predesignated target antibody to a mycobacterium in a sample selected from one or more patient bodily fluids which comprises: (a) a lateral-flow assay comprising a membrane, (b) a conjugated label pad, and (c) at least one mycobacterium antigen bound to the membrane.

12. The immunoassay kit of claim 11, wherein the at least one mycobacterial antigen specifically binds to *Mycobacterium tuberculosis* specific antibodies.

13. The immunoassay kit of claim 11, wherein the at least one mycobacterium comprises two or more mycobacterial antigens.

5 14. The immunoassay kit of claim 11, wherein the at least one mycobacterium antigen is selected from the group consisting of 38kDa and 16kDa antigens.

15. The immunoassay kit of claim 11, wherein the membrane has at least a first stripe of the at least one mycobacterium antigen, and a control stripe formed by striping a material that will react with sample antibodies as they flow across the control stripe.

16. The immunoassay kit of claim 11, wherein the membrane has a least a first stripe of at least one mycobacterium tuberculosis antigen, a second stripe of at least one mycobacterium antigen that is different from the mycobacterium tuberculosis antigen of the first stripe, and a control stripe formed by striping a material that will react with sample antibodies as they flow across the control stripe, the second stripe located between the first stripe and the
15 control stripe.

17. The immunoassay kit of claim 16, wherein the second stripe comprises a shared mycobacterial antigen common to all mycobacteria or a mixture of such antigens.

18. The immunoassay kit of claim 11, wherein the conjugated label pad comprises Protein A.

20 19. The immunoassay kit of claim 18, wherein the conjugate label is colloidal gold.